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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,434	05/11/2001	Grace Wong	49854 (72024)	7250

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EXAMINER

SPECTOR, LORRAINE

ART UNIT PAPER NUMBER

1647

DATE MAILED: 12/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS**OFFICE ACTION SUMMARY**☒ Responsive to communication(s) filed on 10/4/02☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).**Disposition of Claims**

- ☒ Claim(s) 1-11 is/are pending in the application.
Of the above, claim(s) 2, 4, 6, 8-11 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 3, 5, 7 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1-11 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Part III: Detailed Office Action

Restriction Requirement:

Applicant's election with traverse of Group I, claims 1, 3, 5 and 7, with an election of species of carbonic anhydrase 6 gene from Table 3 in Paper No. 5 filed 10/4/02 is acknowledged. The traversal is on the ground(s) that the invention is not directed to specific genes, but rather to a method of identifying specific genes in response to FSH. This argument has been fully considered but is not deemed persuasive because the method requires the search and consideration of each and every gene specifically recited in the claims, for determination of whether that *particular* gene was known to be induced by FSH. Accordingly, each such gene must be separately searched, and it would be an undue burden to examine the full scope of the claim. The Examiner notes that the generic concept of assaying for genes whose expression is induced by FSH is anticipated by the prior art (see below). Further, there is no unity of invention of the Markush group, as although the members of the group share a common utility in the claimed methods, they share no "substantial structural feature disclosed as being essential to the utility. Accordingly unity of invention is lacking, and the species election requirement is proper. See MPEP 803.02.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 3, 5 and 7 are under consideration.

Formal Matters:

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Objections and Rejections under 35 U.S.C. §112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 5 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite

for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5 The claims are indefinite for referring to Tables 1, 2 and 3 in parenthesis; it cannot be determined whether such is exemplary, or whether such is a claim limitation. The claims are further indefinite as the identifying information of Tables 1, 2 and 3 is not such that a person reading the claims would be apprised of their scope: Numerous of the sequences of Tables 1, 2 and 3 are not so identified that one reading this application would have any idea what the actual sequences were. The mere mention of a sequence name, such as "ESTs, highly similar to ..." or IMAGE EST, which is arbitrarily given and contains no specific identifying information, is not sufficient to inform the reader what the actual sequence is. Without such, the metes and bounds of the claims cannot be determined.

10 The claims are further indefinite because they call for identification that expression is "different" (claims 1 and 3), "increased" (claim 5) or "altered" (claim 7). These terms are relative terms which render the claims indefinite. It is not clear by how much the expression must be different, increased, or altered to be significant; one of ordinary skill in the art would expect at least minor variations due to the assay methods used, even if two cells were expressing the genes in equal amount. The terms are not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

15 Claim 5 is further indefinite for reciting "a patient"; it is not clear to what species said patient might belong. As the genes of the three tables *appear* to be mouse genes (although the Examiner cannot determine such unequivocally), it is not clear how one can identify mouse genes in an animal of another species, including human.

20 Claim 7 is also indefinite as the meaning of the number "20" in part C of the claim is not clear.

25 Claims 1, 3, 5 and 7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject

matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

5 As stated above, Tables 1-3 list a number of identifiers of genes, but fail to indicate what the sequences are (which sequences are necessary to practice the claimed methods), nor do they provide clear identification of the intended sequences, nor where such can be obtained. As such is essential to the practice of the invention, the written description fails to support the claims. Further, the specification states at page 4 that the tables are "based on the Incyte, Inc. mouse cDNA array." This is not a disclosure of sequences contained in such array, as such is proprietary, is not static, and is
10 not available to the Examiner or to the public at large, and the Examiner cannot determine how the tables are "based" on such, nor whether the designations therein can be correlated to specific sequences. Further, the specification states that the genes of Table 1 are upregulated in "Y1" cells, but fails to identify those cells; a search of the ATCC website revealed no cell lines designated "Y1", so they appear not to be publicly known. Accordingly, in addition to not identifying the particular
15 genes, the specification does not even provide an adequate written description of what cells the genes were isolated from, nor even the species of animal of origin.

It is further noted that as no specific reference has been given for each of the sequences in the tables, it cannot be considered that such have been incorporated by reference (although such incorporation by reference would itself be improper).

20

Claims 1, 3, 5 and 7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Because the written description fails to support the claims, it cannot be determined how to
25 practice the invention; one of ordinary skill in the art, reading this specification would not be able to determine what sequences would be used for detection.

The Examiner cannot further evaluate the scope of enablement, with respect to what species

would be enabled if the above were overcome, as it is not clear from what species the genes were identified, nor to what species such would be extrapolatable.

5 **Rejections Over Prior Art:**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

10 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated, by Kameda et al., Biochem. Biophys. Acta 1445:31-38.

15 Kameda et al. identified rat ovarian genes that were induced by FSH, via subtraction cloning. One such gene identified was CREM, cAMP responsive element binding modulator (see abstract). At page 35, they disclose that CREM expression was induced by FSH, as detected by Northern blotting, and that the expression was transient, abating by 6 hours after FSH exposure. Therefore, the disclosure of Kameda et al. anticipates the method steps of claims 5 and 7 (wherein the "agent" of claim 7 is FSH).
20

The examiner is unable to determine whether the CREM is one of the genes of Tables 1-3, due to the lack of adequate written description (see above). However, as such cannot be clearly interpreted as being a claim limitation (see rejections under 35 U.S.C. § 112, second paragraph, above), the Kameda disclosure anticipates the claims on the basis that CREM meets the limitation of being an FSH stimulated gene.
25

Claims 1, 3, 5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Orly et al., Endocrinology 134:2336-46.

Orly et al. disclose that the tyrosine kinase inhibitor AG18 arrests FSH-induced granulosa cell differentiation (title). The assay used examined FSH-induced expression of P450scc mRNA, aromatase cytochrome p450, and 3 β -hydroxysteroid dehydrogenase-I, and states that all were inhibited by AG18 at their mRNA levels.

5 As above, the examiner is unable to determine whether the genes assayed by Orly et al. are present in Tables 1-3, due to the lack of adequate written description (see above). However, as such cannot be clearly interpreted as being a claim limitation (see rejections under 35 U.S.C. § 112, second paragraph, above), the Orly et al. disclosure anticipates the claims on the basis that those genes are FSH-stimulated genes.

10

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Jiang et al. disclose the structure of the carbonic anhydrase VI gene. The protein encoded by the gene is stated to be secreted from cells, and to have a role in pH regulation in saliva and a protective effect in the esophagus and stomach (page 389). There is no disclosure that expression of the gene is induced by FSH.

15

WO99/64627 discloses methods of genetic profiling, in which the expression patterns of tissues or cells in response to various stimuli are characterized.

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Advisory Information:

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz,